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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,139	01/28/2004	Stefan Schreck	ECV-5541DIVCON	1979
30452	7590	05/11/2006	EXAMINER	
EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/766,139	Applicant(s) SCHRECK, STEFAN	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-37 is/are pending in the application.
- 4a) Of the above claim(s) 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/23 1/28</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 18-28, drawn to a heart valve, classified in class 623, subclass 2.1.
- II. Claims 29-37, drawn to a method of implantation, classified in class 623, subclass 902.

The inventions are distinct, each from the other because of the following reasons:

Inventions I. and II. are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used by a different process, such as use as a teaching tool/model therefore not implanted at all, or it also could be implanted by non-minimally invasive techniques, such as opening the chest and sewing the valve in place.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with David Hauser (Registration No. 42,643) on April 13, 2006 a provisional election was made to prosecute the invention of Group I., claims 18-28.

Art Unit: 3738

Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-37 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites, “valve leaflets attach to the support structure at least in part by stitching along”. There are two problems with this claim. The word “attach” is in the function form and is currently being treated as intended use language, as to attach. It is suggested to change “attach” to recite --are attached--. Further, the term “by stitching” is a functional limitation and it is noted to the applicant that stitches are not required by the claim. This limitation may be treated as a product by process limitation, see MPEP 2113. If applicant intended to claim stitches, it is suggested to change “stitching” to --stitches--.

Referring to claims 27 and 28, these claims are indefinite, since “sterile container” is not part of a “two-part prosthetic heart valve” as claimed in the preamble. The limitations are out of scope of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-22 and 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Garrison et al. (US 6,425,916 B1, cited in IDS). Garrison discloses a valve (fig.9) comprising a tissue engaging base portion (8, 8A) that is expandable (fig.7, 8), a leaflet subassembly (6, 6A) including a metallic support (26) and three valve leaflets (38; fig.11) attached to the support at commissures (32), wherein the subassembly (6, 6A) is *attachable* to the tissue engaging base portion (8, 8A; see fig.9; col.2, lines 17-20).

Garrison discloses the support (26) to comprise an elastic wireform with cusps (valleys) and commissures (peaks), wherein the leaflets (38) are attached to the wireform (see fig.10, 11, 29, 30). Garrison discloses the support (26) to be self-expanding (fig.29, 30; col.2, lines 12-16; col.8, lines 16-21). Garrison discloses the valve leaflets (38) formed of bioprosthetic tissue (col.5, lines 44-46). Garrison discloses the tissue engaging base portion (8, 8A) to be either plastically or self expanding (col.2, lines 1-5; col.9, lines 2-10). Garrison discloses the tissue engaging base (8) and support (6) to be two separate structures, therefore, inherently they are *capable of being* stored separately before implantation.

Claims 18-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Eberhardt (US 6,350,282 B1, cited in IDS). Eberhardt discloses a valve comprising a tissue engaging base (54, comprising 46+47) portion that is *expandable* (because the base is made of a flexible material, it is capable of being flexed, folded, etc, therefore it is *expandable*), a leaflet subassembly

including a metallic support (36) and three valve leaflets (26, 28, 30) attached to the support (36) at commissures (fig.6, 7), wherein the subassembly is *attachable* to the tissue engaging base portion (see fig.7).

Eberhardt discloses the support (36) to comprise an elastic wireform with cusps and commissures (fig.2), wherein the leaflets (26, 28, 30) are attached to the wireform (fig.7). Eberhardt discloses the support (36) to be self-expanding (col.4, lines 64-67). Eberhardt discloses the valve leaflets (26, 28, 30) formed of bioprosthetic tissue (col.4, lines 28-37). Eberhardt discloses the support to have a fabric covering (48), the three leaflets (26, 28, 30) attached to the support (36) by stitches (56).

Claims 18-24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Carpentier et al. (US 6,558,418 B2). Carpentier discloses a valve comprising a tissue engaging base (48) portion that is *expandable* (because the base is made of a flexible material, it is capable of being flexed, folded, etc, therefore it is *expandable* col.10, lines 59-64), a leaflet subassembly including a metallic support (70) and three valve leaflets (42) attached to the support (70) at commissures (fig.8), wherein the subassembly is *attachable* to the tissue engaging base portion (see fig.8, 11).

Carpentier discloses the support (70) to comprise an elastic wireform with cusps and commissures (fig.4B), wherein the leaflets (42) are attached to the wireform (fig.11). Carpentier discloses the support (70) to be self-expanding (col.7, lines 25-32). Carpentier discloses the valve leaflets (42) formed of bioprosthetic tissue. Carpentier discloses the support (70) to have a

Art Unit: 3738*


fabric covering (72; col.7, lines 19-20, 60-63), the three leaflets (42) attached to the support (70) by stitches (col.10, lines 1-5).

Conclusion

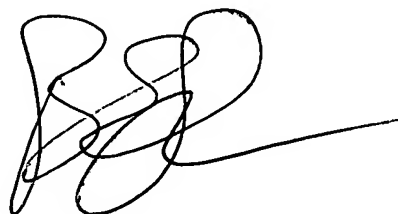
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER